FINAL/APPROVED (09/27/2006)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

Monday, June 5, 2006
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the Board of Pharmacy was called to order at 9:04 a.m.

PRESIDING: Leo H. Ross, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
John O. Beckner
Willie Brown
Bobby Ison
David C. Kozera
Diane Langhorst
Mark A. Oley
Michael E. Stredler

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Ralph Orr, Program Manager, Prescription Monitoring Program
Tiffany N. Mallory, Administrative Assistant

QUORUM: With nine members of the Board present, a quorum was established.

Ms. Reiniers-Day reviewed the emergency evacuation procedure for conference room 2.

APPROVAL OF AGENDA: Mr. Beckner moved, and the Board voted unanimously to approve the agenda as presented.

APPROVAL OF MINUTES: Mr. Brown moved, and the Board voted unanimously to approve the March 8, 2006, minutes as presented.

Mr. Ross thanked the Board members and staff for their contributions accomplished during his first term as a Board member and Chairman for the Board of Pharmacy.

Mr. Ross recognized Mr. Oley for comments. Mr. Oley stated that as this was his last meeting, he wanted to thank his fellow Board members and staff for the work accomplished during both his terms on the Board.

PUBLIC COMMENT: Becky Snead, Executive Director for the Virginia Pharmacist Association (VPhA), expressed her concern about oversight of

pharmacies in implementing the new restrictions on the sales of pseudoephedrine. She had been informed that in some cases both DEA agents and state police agents had been in pharmacies advising pharmacies of how they needed to comply with new requirements and in most cases were providing erroneous information. Ms. Russell stated that she was attending a DEA conference starting the next day and would attempt to find out about the DEA enforcement effort. Ms. Snead stated that some coordination between the state and federal persons who were enforcing these provisions needed to occur, along with a comprehensive guide that incorporated the requirements of both laws. Ms. Russell stated that Board staff was in the process of trying to update information on the website.

LEGISLATIVE PROPOSAL TO UPDATE § 54.1-3315, § 54.1-3316 AND§ 54.1-3322:

Ms. Russell advised that the Board has sometime had difficulty in determining the grounds to take disciplinary action against pharmacists and pharmacy technicians. She discussed the need to add language to § 54.1-3315, § 54.1-3316 and § 54.1-3322 with respect to unprofessional conduct and diversion of drugs. It was determined that it would be best to repeal § 54.1-3415, incorporating those concepts into § 54.1-3416, and giving the Board authority to further define "unprofessional conduct" in regulation, and add "diversion of controlled substances" as another ground for disciplinary action. Ms. Yeatts suggested that staff review the Board of Medicine statute for guidance in how to word the proposal. After further discussion, Mr. Beckner moved, and the Board voted unanimously to adopt the draft legislation in concept with Ms. Russell, Mr. Casway and Ms. Yeatts incorporating the appropriate language.

LEGISLATIVE REMINDERS:

Ms. Russell reviewed legislative actions of the 2006 General Assembly that had some impact on the practice of pharmacy or the Board. Ms. Russell stated that the ad-hoc pedigree committee needs to resume working on regulations and that she was looking for a date in July for the Committee to meet. She will begin contacting members by e-mail beginning next week to establish a meeting date.

Ms. Yeatts provided a handout of the Virginia Acts of Assembly-2006 session, and proceeded to explain Section 19 of § 54.1-3005. The Board of Nursing in consultation with the Board of Pharmacy must develop training guidelines for employees of child day programs to administer prescription drugs. Ms. Yeatts informed the Board that The Department of Social Services has already started approving curriculums and programs in order to facilitate the training process. She also suggested that the consultation be delegated to Board staff. Ms. Abernathy moved and the Board voted unanimously to delegate child day program consultation with the Board of Nursing to staff.

UPDATE ON REGULATION PROCESSES

Ms. Yeatts presented the Board with an overview of all ongoing regulations in process.

ADOPTION OF PROPOSED REGULATIONS ON COLLABORATIVE PRACTICE AGREEMENTS:

Ms. Russell informed the Board that a joint committee between the Board of Pharmacy and the Board of Medicine met to draft the proposed regulations governing collaborative practice agreements. Ms. Russell also stated that, upon adoption of the regulations by the Board, the draft regulations would then need to be adopted by the Board of Medicine before they could be sent for publication. A concern was raised on 18VAC110-40-20 Section B, paragraph 2 on the issue between informed consent between the practitioner and the patient and whether the language in 18VAC110-40-50 Section C was a burden in creating unnecessary paperwork. Mr. Beckner moved and the Board voted unanimously to adopt the Collaborative Practice Agreements regulations as proposed by the Committee and amended by the Board as follows: 18VAC110-40-20 section B, paragraph 2 shall read: "Prior to giving consent to participate, the patient shall be informed by the practitioner or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record", and 18VAC110-40-50 to shall read: "The patient's documented informed consent shall be retained by the practitioner in the patient record".

RESPONSE TO PETITION FOR RULE-MAKING:

To follow-up from the March Board meeting, Ms. Russell informed the Board that she had that spoken with Meron Endale and that Ms. Endale indicated that she was not really interested in changing the regulation, as originally thought, but that she wanted immediate relief from the Board. She had worked about seven months as a "technician in training" without realizing that she could have registered with the Board as a pharmacy intern. Ms. Endale wanted the Board to count the months that she been working towards her practical experience hours as a pharmacy technician in training. Mr. Stredler moved and the Board voted unanimously to deny Ms. Endale's petition for rule-making.

REVISION OF GUIDANCE DOCUMENT 110-17 RELATED TO PHARMACY INTERN REGISTRATION:

Ms. Russell stated that Virginia is one of three states that has been allowing foreign graduates to obtain a Pharmacy Intern license while they wait to take the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) and that other states require that the applicant pass the FPGEE before gaining practical experience. Ms. Russell stated that the current Guidance Document does not conform with current statutes, and that staff has been in error by allowing the applicants to register as interns before passing the FPGEE and tests of English. Ms. Russell requested that the Board approve the changes in Guidance Document 110-17 so that it would be in conformity with § 54.1-3300 (definition of a pharmacy intern), § 54.1-3312 of the Code and 18VAC110-20-70 of the regulations. There was some discussion as to the order of some of the information in the guidance document. Staff agreed to reorder the information for clarity, and correct a grammatical error wherein the

word "be" was inadvertently left out. Ms. Langhorst moved and the Board voted unanimously to approve Guidance Document 110-17 as amended, with the substantive change being to require passing of the FPGEE and required tests of English prior to allowing a graduate of a foreign college of pharmacy to register as a pharmacy intern.

REVISION TO GUIDANCE DOCUMENT 110-36; RELATED TO EXTENDING DATE FOR COMPLIANCE WITH USP 797 PHYSICAL REQUIREMENTS:

Ms. Russell informed the Board that the ad hoc committee, which was appointed in the March meeting to review this Guidance Document has not met. As mentioned at the March Board meeting JACHO, is no longer enforcing the original deadline of June 30, 2007, for hospitals and pharmacies to be in compliance with the physical standards for sterile compounding in USP Chapter 797. Ms. Russell presented the Board with a revised Guidance Document that would extend the deadline for compliance with physical standards until June 30, 2008. Ms. Russell commented that many of the hospitals are having difficulty with the expense of making these changes, and the extension of the deadline would give them about two years to comply. Ms. Russell advised that, should the revised Guidance Document be approved, it would be placed on the Board of Pharmacy website as soon as possible. Mr. Ison moved and the Board voted unanimously to approve the revised Guidance Document 110-36 as presented.

REVISION TO GUIDANCE DOCUMENT 110-38 ON ACCEPTABLE INSPECTION ALTERNATIVES FOR NON -RESIDENT PHARMACIES AND BOARD BYLAWS FOR NON-RESIDENT PHARMACIES:

Ms. Russell informed the Board that many non-resident pharmacies, particularly North Carolina, are not providing inspection reports upon submitting an application with the Board. She acknowledged that some states do not conduct inspections for their pharmacies or, if they do, the inspections are dated five years or older. After July 1, 2006 the Board will have the authority to accept inspection reports conducted by other agencies, or inspect the pharmacies themselves. Ms. Russell presented a revised Guidance Document 110-38 that showed NABP and JCAHO as two organizations that the Board would consider acceptable inspection sources. Discussion included rearranging the guidance document for clarity. After further discussion, Mr. Beckner moved and the Board voted unanimously to adopt the guidance document as presented with staff reordering some of the language. Further, Ms Russell presented revised bylaws as it relates to non-resident pharmacies. Section 14 under Article V of the bylaws was added, that delegates to the Executive Director authority to accept inspection reports by entities not specifically listed on the guidance document and to request inspections of non-resident pharmacies by the agents of the Board. Minor changes were also made to the language in sections four and 12 under Article V. Mr. Oley moved and the Board voted unanimously to adopt amendments to the bylaws as presented.

REVISION TO GUIDANCE DOCUMENT 110-26 RELATED TO PHARMACIES THAT

Ms. Russell presented a revised Guidance Document 110-26 to include proposed changes to numbers 1 , 2 , 4 , and 7 regarding inspection violations for pharmacies. Ms. Russell stated to the Board that recent inspections indicated that pharmacies have been

MOVE OR REMODEL WITHOUT SUBMITTING AN APPLICATION:

remodeling by installing new alarm systems or other types of items without submitting a remodeling application and sometimes the remodeling occurred one to two years prior to the routine inspection. The current document allowed the pharmacy just to submit a remodeling application and pay a fee, but Ms. Russell contended that submitting an application two years after the fact makes no sense, and that there is really no penalty for not submitting it in the first place. After further discussion, Mr. Stredler moved, and the Board voted unanimously to adopt amendments to Guidance Document 110-26 as presented and with the following amendments: Section one,1st Time Cited shall read: "Allow to fix, pay reinspection fee; if necessary" and 2nd time cited shall read: $250 and pay reinspection fee if necessary". Section two, 1st Time Cited shall read: "Allow to fix, pay reinspection fee; if necessary." Section seven shall read: "$250 and fix anything not in compliance; if necessary, 2nd Time Cited, Informal Conference."

NEW GUIDANCE DOCUMENT 110-11 RELATED TO 18VAC 110-20-550:

Ms. Russell stated that there is now a need for a guidance document regarding Board of Pharmacy Regulation 18 VAC 110-20-550, and presented a draft document to the Board. She explained that the regulation allows a stat-drug box for first doses to be provided to a long term care facility where only persons licensed to administer drugs are administering drugs in the facility. Ms. Russell stated that the original intention of this regulation was to prohibit stat-drug boxes in assisted living facilities that used medication aides to administer medications, but that the population in assisted living facilities has shifted over the past few years to include more patients with serious or complex health issues, and that many assisted living facilities, while using medication aides to administer routinely self-administered medications, also have nurses available on staff 24-7. Because of the population shift in these facilities, there is frequently a need for first doses at times when the pharmacy cannot reasonably provide them, and that availability of a stat-drug box that would only be accessed by a nurse (or pharmacist or prescriber), would improve health care for these residents. Ms. Yeatts suggested that the Board include language to specifically state that medication aids cannot access or administer drugs from the stat-drug box. Ms. Abernathy suggested to include the language "upon order from the prescriber" for use of the box. Mr. Oley moved and the Board voted unanimously to adopt Guidance Document 110-11 as presented with the following amendments. It shall read: "Board of Pharmacy Regulation 18 VAC110-20-550 is interpreted to allow stat-drug boxes to be provided for use in long term care facilities, to include assisted living facilities that use medication aides to administer routine medications, under the condition that there is an order by a prescriber for any drug removed from the stat-drug box, and that only a licensed nurse, pharmacist, or prescriber be allowed to access or administer a drug from the stat-drug box. Medication aides may not access or administer

medications from this box."

ELECTION OF CHAIRMAN AND VICE CHAIRMAN

Mr. Oley moved and the Board elected unanimously John Beckner as the Chairman for the Board of Pharmacy.

Mr. Beckner moved and the Board elected unanimously Bobby Ison as the Vice-Chairman for the Board of Pharmacy

REPORT ON THE BOARD OF HEALTH PROFESSIONS

Ms. Russell provided a handout summarizing the most recent meeting of the Board of Health Professions. She reminded the Board that Ms. Aust resigned from the Board as of May 8, 2006 as she has been employed by the Department of Health Professions as an inspector.

EXECUTIVE DIRECTOR'S REPORT

Ms. Russell provided an update to the Board on her attendance at the annual NABP conference. NABP has Eight districts and Virginia is located in District Two. There will be an opening for an Executive Committee member from District II next year, and Ms. Russell is interested in being nominated by the District for this opening.

Ms. Russell announced that she would be leaving that day to attend the annual DEA conference.

Ms. Russell and Mr. Orr will be attending the Bureau of Justice Assistance grant workshop from June 13-15, 2006 for the Prescription Monitoring Program.

Ms. Russell and Ms. Juran are planning to attend a one day workshop given by the EPA in Washington, D.C., on information regarding destruction of drugs. Ms. Russell informed the Board that many hospitals are putting syringes and drugs in bio-hazard boxes, which is unacceptable practice. The EPA is holding this workshop to meet with state officials to educate on the appropriate methods of drug destruction.

Ms. Russell stated that the first newsletter was published in May and that the Board would like to continue sending newsletters and future correspondence by e-mail. However, many of the pharmacists have not provided the Board with their e-mail addresses. There about 9,000 pharmacists licensed in the Commonwealth. The Board only has about 5,000 e-mail addresses in the database.

Betty Jolly, Assistant Director for Policy Education, provided an update on the retreat. After discussing the matter further, the Board decided to hold the retreat in December rather than September. The dates chosen for the retreat are December 12, 2006 and December 13, 2006.

Ms. Reiniers-Day gave a report regarding the Board's disciplinary caseload and stated that there were currently 250 cases being investigated by the Enforcement Division and 98 cases with the Board, however, 43 were with the Administrative Proceedings Division, six were at the informal conference level and one was at the formal hearing level. The Compliance Division was tracking 164 individuals and has 47 cases opened regarding non-compliance issues or additional allegations.

Ms. Russell, reviewed the number of current active licensees issued up until today. The Board issued 105 Controlled Substance Registrations, with most of those being community services Boards. Ms. Russell informed the Board that recently they have received a lot of controlled substance registration applications for correctional facilities who operate medical offices within the facilities and are in the process of issuing their licenses as well.

Mr. Orr reviewed with the Board the progress for the Prescription Monitoring Program. An article about the program was featured in *The Ronoake Times* and *Washington Post* during the month of June. The program has begun to collect data statewide for Schedules II, III, and IV controlled substances. Mr. Orr also mentioned that pharmacists can now go online and make requests, and that since this has been available, 25% of the requests have come in through the data center. Currently, the program contains 2.2 million records and has received 1,216 requests for information.

NEW BUSINESS: Ms. Abernathy requested a report on all the Board's pilot programs for the September Board meeting.

ADJOURN: With all business concluded, the meeting adjourned at 11:26 a.m.

Elizabeth Scott Russell
Executive Director

Leo H. Ross, Board Chair

Date